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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/786,937	01/22/1997	PHILIPPE BOUCHARD	098501-0235299	5859

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/786,937	BOUCHARD ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-39, 42, 44-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 38,39,42,44-51,56-63,65,67-70,72-75,78-80,83,84,86-92,94-100,102-105,107,108,110-116,118,119,121-123 and 126-141.

DETAILED ACTION

Formal Matters

The amendment filed 13 March 2007 is acknowledged. Claims 38, 39, 44, 51, 56, 61-63, 65, 67-70, 72-75, 78-80, 83, 86, 94, 99, 100, 102-105, 107, 108, 110-115, 118, and 119 and 126 are currently amended. Claims 40, 52-55, 71, 81, 82, 106, 120, 124 and 125 are canceled, and claims 129-141 are new. Claims 38-39, 42, 44-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112, first paragraph

The rejection of claims 38-40, 44-50, 61-63, 65, 67-72, 83-84, 86-91, 99-100, 102-107, 115-116 and 118-128 under 35 U.S.C. 112, first paragraph for scope of enablement is withdrawn in response to Applicants' cancellation of claims 40, 71, 106, 120, 124 and 125 and furthermore, in response to Applicants' amendment of the claims. Applicants have amended the claims to recite "a combination of luteinizing hormone (LH) and follicle stimulating hormone (FSH)", which one of skill in the art would recognize as being the components of hMG. Applicants have further amended the claims to recite specific LHRH antagonists.

The rejection of claims 83-128 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in response to Applicants' cancellation of claims 106, 120, 124 and 125 and furthermore, in response to Applicants' post-filing date evidence in the form of Felberbaum et al. and Huirne et al. (cited by Applicants, only abstracts provided), that multiple doses of 0.25 mg Cetrorelix was effective in COS/ART treatment regimens.

Claim Rejections - 35 USC § 102

The rejection of claims 38-39, 42, 45, 46, 48, 49, 50, 51, 52, 56, 57, 58, 60, 61, 62, 65, 67, 68, 69, 71, 72, 73, 74, 78, 79, 80, 82 under 35 U.S.C. 102(b) as being anticipated by Olivennes et al. (Fertil Steril. 1994. 62: 468-476—cited on Applicants 1449 form submitted 3 August 2004) is withdrawn in response to Applicants' cancellation of claims 52, 71 and 82 and Applicants amendment of the claims to recite administration of a 3 mg dose (claims 38, 51 and dependents) and the amendment of the claims to recite "without the administration of a hormone or hormone agonist to induce ovulation" (claim 61 and dependents, which also specify LHRH dose).

The rejection of claims 40, 52, 53, 61, 62, 63, 65, 67, 68, 71, 72, 73, 74, 75, 78, 79, 80 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al. Hum Reprod. 1994; 9: 788-791—cited on Applicants 1449 form 22 June 1998) is withdrawn in response to Applicants cancellation of claims 40, 52, 53, 71 and 82 and Applicants amendment of the claims to recite "without the administration of a hormone

or hormone agonist to induce ovulation" (claim 61 and dependents, which also specify LHRH dose).

Double Patenting

The provisional rejection of claims 52, 71, 81, 82, 106, 120, 124 and 125 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 26-42 of copending Application No. 10/661,780 is withdrawn in response to Applicants' cancellation of those claims.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 38, 39, 42, 44, 45, 46, 48, 49, 50, 51, 52, 53, 56, 57, 58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al. (cited above) is maintained for reasons of record and the following.

The claims are drawn to a method for obtaining the production of a fertilizable oocyte within a program of controlled ovarian stimulation for assisted reproduction techniques (COS/ART) comprising: (a) administering an exogenous gonadotropin to induce follicle growth, and (b) administering a luteinizing hormone releasing hormone

(LHRH) antagonist to prevent a premature LH surge, wherein the LHRH antagonist is administered in a single or dual dosage regimen of 1 to 10 mg per dose beginning on menstruation cycle day 1 to 9 and wherein follicular growth occurs in the absence of an LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected, wherein the dosage of LHRH antagonist 3 mg per dose and is administered by subcutaneous injection, wherein the LHRH antagonist is administered starting cycle day 4 – 8 or 6 – 10 and ovulation occurs between day 9 – 16 of the menstruation cycle or wherein ovulation occurs within 6.5 days following administration of a single or second dose of the LHRH antagonist, wherein ovulation occurs without the administration of a hormone or hormone agonist to induce ovulation, or wherein ovulation is induced by administering a hormone or hormone agonist to induce ovulation and the hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist and hCG, wherein the LHRH antagonist is Cetrorelix.

Diedrich et al. teach a method comprising administration of hMG each day starting on day 2 of the cycle, followed by daily subcutaneous doses of 3mg of Cetrorelix starting on day 7 of the cycle and continued until induction of ovulation was achieved with the administration of 10,000 IU of hCG. (See p. 789, left column under Ovarian stimulation for IVF and right column, Figure 2 for a schematic of treatment regimen). The method steps recited in the claims are the same as those taught by Diedrich et al. The claims recite additional limitations in the form of effects of the

treatment, such as "wherein follicular growth occurs in the absence of an LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 (or day 9 – 16) of the menstruation cycle, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected," but these effects would be achieved by the methods taught by Diedrich et al. because they teach the same method steps to the identical patient population (women undergoing ART). Note MPEP 2112, I. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition [or method] patentably new to the discoverer."

Applicants argue at p. 23, last 2 paragraphs of their remarks that Diedrich et al. do not describe a method comprising administering an LHRH antagonist in a single or dual dosage regimen of 3 mg per dose to prevent a premature LH surge, however, the differences between what is taught by Diedrich and what is recited in the claims are very slight. Diedrich et al. teach administration of hMG followed by multiple subcutaneous doses of 3mg Cetrorelix until ovulation is achieved. The claims are written using "comprising" language, and there is no language excluding the administration of hCG to induce ovulation (as there is in amended claim 61 and its dependents), thus the claim cannot be distinguished over the Diedrich et al. The intended purpose of the claim recited as "to prevent a premature LH surge," is not sufficient to distinguish over the prior art because the prior art teaches the same method steps.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 38-39, 42, 45-51, 56-62, 65, 67-74, 78-82, 86-92, 94-100, 102-105, 107-108, 110-116, 118-119, 121-123, 126-128 and new claims **129-141** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 26-42 of copending Application No. 10/661,780 is maintained for reasons of record and the following. In addition, due to a typographical error, claims **63, 75 and 83-84** were erroneously left out the rejection and are hereby included. Applicants' request deferral of this issue until other issues of patentability are resolved in their response filed 13 March 2007 is noted. However, deferral of arguments is not proper; an argument after the claims have been found otherwise allowable that obviousness type double patenting does not exist will not be considered

timely. Accordingly, the provisional rejection is maintained. Note that this is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

Christina Borgeest, Ph.D.

ELIZABETH KEMMERER
PRIMARY EXAMINER